COMFORT
COMFORT ORTHOPEDIC CO., LTD. www.comfort.com.tw
No.120,Nan Shiang Tsuen,Shoei Shang Shiang,Chia-yi, 60858, Taiwan, R.O.C.
TEL : 886-5-2892093 FAX : 886-5-2890070

K102734

" 510(k) SUMMARY "

DEC 14 2010

Submitter's Name: ***COMFORT ORTHOPEDIC CO., LTD.***
N0. 120, NAN SHIANG TSUEN, SHOEI SHANG SHIANG, CHIA-YI, 60858, TAIWAN, ROC

Date summary prepared: August 23, 2010

Device Name:

Proprietary Name:	COMFORT Standing Wheelchair, HERO series
Common or Usual Name:	Standup Wheelchair
Classification Name:	WHEELCHAIR, STANDUP, Class II, 21 CFR 890.3900
Product code:	IPL

COMFORT Standing Wheelchair, HERO series including:

- LY-ESA120 (HERO 3),
- LY-ESA120-N (HERO 3-N),
  All of the specifications are same as LY-ESA120 (HERO 3) just different headrest.
- LY-ESA140 (HERO 4)
  All of the specifications are same as LY-ESA120 (HERO 3) but made by steel for the frame; and the HERO 3 and HERO 3-N are made by aluminum.

Indications for Use:

The device is a product which changes people position not only from sitting to standing and standing to sitting but also reclines and lifts the seat and back position. The product provides indoor and outdoor mobility

Description of the device:

The COMFORT Standing Wheelchair is an indoor / outdoor standup wheelchair that is manual wheelchair, not an electric power wheelchair, with an electric power standing wheelchair. The electric power is not used to move the wheelchair but to stand the patient.

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Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3: 1995 (Electrically Powered Wheelchairs, controller, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

COMFORT Standing Wheelchair, HERO 2 (K031618)

Summary for substantial equivalence comparison:

Compare to the new device and predicate device, the overall dimensions and visional appearance are similar, and the electronic systems between the two devices are all passed by the UL certificated, for instance the **electronic controller**, **batteries**, and **recharge**. Besides, the **back upholstery** is the same material, and also passed the resistance ignition test by SGS. Moreover, the suspension of cross brace, footplates, incline degree 12°, armrest type, the size of tires, the weight limit, and warranty are all the same. The safety and performance functions of two systems are assured and validated. They are substantially equivalent.

Besides, we would like to emphasize that the new device and predicate device are also the Standing Wheelchairs which are the manual wheelchair, not the electric power wheelchairs, with an electric power standing wheelchair. The electric power is not used to move the wheelchair but to stand the patient.

Based on the above the information and the analysis, we know that the subject device and the predicate device have the same intended use, the same technological aspects and only minor differences exist. We believe that FDA can decide the subject device and the predicate device are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Comfort Orthopedic Co., LTD
% Mr. Eric H. C. Lee
No. 120, Nan Shiang Tsuen
Shoei Shang Shiang
Chia-Yi 60858, Taiwan, R.O.C.

DEC 14 2010

Re: K102734
Trade/Device Name: COMFORT Standing Wheelchair, HERO series
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: September 30, 2010
Received: Ocotber 6, 2010

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): **K102734**

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Device Name: *COMFORT Standing Wheelchair, HERO series*

Intended Use:

The device is a product which changes people position not only from sitting to standing and standing to sitting but also reclines and lifts the seat and back position. The product provides indoor and outdoor mobility.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102734